

REMARKS

Claims 1 to 17 remain in this application. Of these claims, Claims 1 and 8 are independent claims.

The specification has been amended to provide the antecedent basis for the subject matter cited in original Claims 2 and 6. Consequently, applicant respectfully submits that the specification now has proper antecedent basis for the recitations appearing in these original claims.

Claims 1 to 17 have been rejected under 35 U.S.C. §103(a) as unpatentable over the United States patent to Foster No. 6,505,079, in view of the United States patent to Limoge No. 3,835,833, further in view of the United States patent to Fischell No. 6,597,138. Applicant respectfully submits that this rejection is improper and that it should be withdrawn. Before entering into a discussion as to the reasons for this position of applicant, however, a brief review of the three references upon which the rejection is based is considered to be in order.

The primary patent to Foster No. 6,505,079 is directed to an apparatus and method for effecting transcranial electrostimulation. The system of Foster is primarily directed to various safety controls for over-current detection, over-voltage detection, and DC

1 offset detection to cause a rapid shutdown of the operation of the
2 system whenever a pre-established threshold of these different
3 parameters is reached. Figure 2 of this patent discloses burst
4 characteristics of a signal which is transmitted through the
5 electrodes. A squarewave signal at a high frequency is produced
6 for an interval (4 milliseconds) and then turned off for a
7 succeeding interval (6 milliseconds), whereupon it again is
8 generated. This constitutes an on/off burst signal at 10
9 millisecond intervals, which is fully on at some pre-established
10 frequency and amplitude for a portion of each interval, and then is
11 fully off (0 amplitude and 0 frequency) for another portion of the
12 repetition interval. There is nothing here of an asymmetrical tone
13 burst which has a first portion of a high amplitude burst, followed
14 by a second portion of a low amplitude burst. The "off" period of
15 Foster is not comprised of any squarewave pulses (or any pulses
16 whatsoever, for that matter).
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18 Column 24 of Foster, Lines 28-34 discusses a sweep frequency
19 range of application within boundaries of about 100 kHz up to 10
20 mHz, with burst frequencies falling within ranges which are within
21 the bounds of about 10 Hz to 1 KHz. Foster also provides a vague
22 reference (with no specifics) in Column 15, Lines 27-29 stating
23 that the practitioner is given "an opportunity to determine whether
24 or not to access a library of waveform parameters", with reference
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1 to Figure 5A which does not provide any specifics about those
2 waveform parameters. What are they? How do different parts of the
3 waveforms relate to one another? Foster does not provide the
4 answers.

5 Foster also refers, in Column 24, Lines 6-10, to adjusting the
6 amplitudes of the positive-going and negative-going complements of
7 the waveform developed in the sweep function to adjust these
8 waveforms within the confines of a zero DC term criterion.
9 Figures 1 and 2 and the description of these figures, found in
10 Columns 5 and 6 of Foster, constitute the only representation of
11 waveforms in conjunction with the Foster disclosure. The
12 shortcomings of the waveform pattern of Figure 2 has been discussed
13 above.
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15 Limoge patent No. 3,835,833 is directed to a system/method for
16 obtaining neuro-physiological effects by amplitude modulating a
17 high frequency signal generated by an oscillator, with an
18 adjustable frequency between 100 kHz and 10 mHz.. In Limoge, the
19 modulated signal then is combined with a "white noise" signal to
20 obtain a composite signal applied to electrodes attached to the
21 patient. Limoge does not disclose any production of asymmetrical
22 tone burst envelopes having two different portions at two different
23 amplitudes, or any asymmetrical pattern variation of pulses.
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25 The United States patent to Fischell No. 6,591,138 is directed
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1 to a low frequency neuro stimulator. Unlike Foster, Fischell
2 utilizes low frequency stimulation in a range of approximately 1 Hz
3 to 10 Hz. As noted by the Examiner, Fischell does describe varying
4 the amplitude of the signal for the duration of the treatment.
5 This is done, however, over a relatively long period of time, and
6 is explained in Column 5, Lines 13-18 as "while the standard
7 treatment would have a constant amplitude for the duration of the
8 low frequency stimulation, it may be advantageous to have the
9 amplitude begin high and decrease over the duration, begin low and
10 increase of the duration, or vary according to any desired
11 treatment plan.". The specific range of "high" and "low" or "vary
12 according to any desired treatment plan" is not described in the
13 Fischell patent.
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15 The Examiner has taken the position that it would have been
16 obvious to adjust waveform components such as amplitude, pulse
17 rate, duration, etc. to achieve the desired therapeutic or
18 investigatory results based on patient needs and bodily
19 characteristics. Apparently, this is the basis for some
20 unspecified manner of combining the teachings of these very
21 different patents together to somehow arrive at applicant's
22 specifically claimed method for effecting transcranial
23 electrostimulation. How does the Examiner propose incorporating
24 anything from the teachings of Fischell into Foster, since these
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1 systems are directed to entirely different types of electrical
2 stimulation, with entirely different frequency ranges? What of
3 Fischell is to be incorporated into Foster? How and why?

4 How does the Examiner propose incorporating anything from
5 Limoge into the combination of Foster and Fischell? Where is there
6 any basis in any of these patents for combining them together in
7 any fashion to form some type of different system/method?
8 Applicant submits that there is no suggestion whatsoever in Foster,
9 Fischell or Limoge of combining them together to arrive at the
10 method and apparatus which is claimed in independent Claims 1 and
11 8 and, therefore, all of the dependent claims, which are
12 dependent, either directly or through one another, upon these two
13 independent claims.
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15 Applicant respectfully submits that modification of Foster,
16 for example with the low frequency signals of Fischell, would
17 destroy both of these patents for their intended purposes. In
18 addition, how is the modulation of Limoge to be incorporated either
19 of these other references without destroying these references for
20 their intended purposes? Applicant respectfully submits that
21 apart from applicant's own specification, there is no suggestion
22 whatsoever of any manner of combining the three references which
23 have been used by the Examiner to reject all of Claims 1-17 under
24 35 U.S.C. §103(a).
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1 As specified in MPEP §2142, in order to properly combine
2 references under 35 U.S.C. §103, "the Examiner must step backward
3 in time into the shoes worn by the 'hypothetical person of ordinary
4 skill in the art' when the invention was unknown and just before it
5 was made." To do this, the Examiner must put aside knowledge of
6 an applicant's own disclosure and refrain from using hindsight to
7 reach a legal conclusion based on facts gleaned from the prior art.

8 As further set forth in MPEP §2142, in order to establish a
9 prima facie case of obviousness under 35 U.S.C. §103, there must be
10 some suggestion or motivation, either in the references themselves
11 or in the knowledge generally available to one of ordinary skill in
12 the art, to combine the teachings. In addition, the teaching or
13 suggestion to make the claimed combination and the reasonable
14 expectation of success, must both be found in the prior art and not
15 be based on an applicant's disclosure. Various cases in support of
16 this are set forth in MPEP §2142; and for that reason, those cases
17 will not be further cited here.
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19 In addition to the foregoing, MPEP §2143.01 clearly sets forth
20 that the mere fact that the references can be combined or modified
21 does not render the resultant obvious, unless the prior art also
22 suggests the desirability of such a combination. In the present
23 case, applicant respectfully submits that it does not appear that
24 the references even can be combined together. Applicant submits
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1 that the requirement of MPEP §2143.01 clearly is absent in the
2 combination of Foster, Limoge and Fischell which the Examiner has
3 made in order to make a sweeping rejection of all Claims 1-17 of
4 this application. MPEP §2143.01 further states that if the
5 proposed modification would render the prior art invention being
6 modified unsatisfactory for its intended purpose, then there is no
7 suggestion or motivation to make the proposed modification.

8 Applicant respectfully submits that in order to make some
9 combination of Foster, Limoge and Fischell as suggested by the
10 Examiner, it is necessary to so substantially modify any one or all
11 of these references that the resultant, whatever it would be, would
12 totally destroy the operation of the devices/methods disclosed in
13 these patents for their intended purposes. For example, to change
14 Foster's high frequency operation to some type of low frequency
15 operation, as disclosed in Fischell, would destroy Foster.
16 Fischell obviously does not contemplate a method applying high
17 frequency pulses. Fischell is specifically directed to a low
18 frequency method for a particular application. At the same time,
19 the incorporation of Limoge into either of these other references
20 produces some type of indeterminate result. Clearly, the
21 utilization of white noise in either Foster or Fischell is not
22 contemplated or even considered. What would be the effect of white
23 noise in the device of Fischell or the device of Foster? Would
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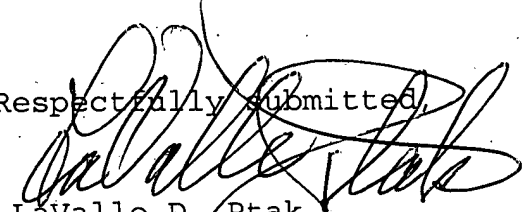
1 either of these systems/methods function properly with a
2 superimposition of white noise on them?

3 Applicant respectfully submits that the only possible
4 suggestion for any combination of Foster, Limoge and Fischell as
5 made by the Examiner, necessarily must come from applicant's own
6 specification. The disclosures of these patents frankly are
7 incompatible for the combination suggested by the Examiner without
8 considerable hindsight teachings from applicant's own disclosure.
9 Applicant respectfully submits that such a rejection clearly falls
10 under the prohibition of MPEP §2103.01 that the mere fact that the
11 references can be combined or modified does not render the
12 resultant combination obvious, unless the prior art also suggests
13 the desirability of the combination. Such a suggestion simply is
14 not present in any of the cited references. Applicant respectfully
15 submits that the only possible suggestion for the combination of
16 the references used by the Examiner in rejecting Claims 1-17
17 necessarily must come from applicant's own specification. This is
18 a hindsight determination, which clearly is set forth in MPEP §2142
19 as impermissible, and which must be avoided.
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22 In view of the foregoing, applicant requests reconsideration
23 and withdrawal of the rejection of the claims of this application.
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1 Applicant respectfully requests allowance of all of the claims of
2 this application; and a formal Notice of Allowance is respectfully
3 solicited.

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5 Respectfully submitted,

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7 LaValle D. Ptak
8 Registration No. 19,877
9 LAW OFFICES OF LAVALLE D. PTAK
10 28435 N. 42nd Street
11 Cave Creek, AZ 85331
12 Telephone: (480) 419-9019

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